

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

LIN

Serial No. 09/084,441

Filed: May 27, 1998

Title: OPHTHALMIC SURGERY METHOD USING
NON-CONTACT SCANNING LASER

Group Art Unit: 3739

Examiner: Michael Peffley

Client Reference: LIN

Attorney Docket: 62-575



October 25, 2000

SECOND SUPPLEMENTAL AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Kindly enter the following amendments and remarks in the above-referenced application.

IN THE CLAIMS

Kindly amend the claims as follows. Unamended claims added in the Reissue application are included for the convenience of the Examiner.

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24. (Thrice Amended) A method for performing ophthalmic surgery comprising:

providing a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, [such that said laser emits a pulsed laser beam having] a repetition rate of 1 Hz to 1000 Hz, and an energy level exiting from said output window of said basic laser of no greater than 10 mJ per pulse [from said laser];

applying said pulsed laser beam onto corneal tissue; and

scanning said pulsed laser beam in a substantially overlapping pattern on said corneal tissue such that adjacent ablation spots on a single ablation layer of said corneal tissue significantly overlap one another.

26. (Not Amended) The method for performing ophthalmic surgery according to claim 24, wherein:

said substantially overlapping pattern is achieved using randomized scanning of said pulsed laser beam on said corneal tissue.

28. (Not Amended) The method for performing ophthalmic surgery according to claim 24, wherein:

said pulsed laser beam has a spot size on said corneal tissue of no greater than 1 mm.

29. (Not Amended) The method for performing ophthalmic surgery according to claim 25, wherein:

said pulsed laser beam has a spot size on said corneal tissue of no greater than 1 mm.

30. (Not Amended) The method for performing ophthalmic surgery according to claim 26, wherein:

said pulsed laser beam has a spot size on said corneal tissue of no greater than 1 mm.

31. 32. (Amended) The method for performing ophthalmic surgery according to claim 24, wherein: [successive]

Δ2 pulses of said pulsed laser beam corresponding to adjacent ablation spots on said single ablation layer overlap one another by [are overlapped] at least 50 percent.

35. (Not Amended) The method for performing ophthalmic surgery according to claim 24, wherein:

said pulsed laser beam is scanned synchronously with said pulses of said pulsed laser beam.

36. (Not Amended) The method for performing ophthalmic surgery according to claim 24, wherein:

an area of corneal tissue 0.05 to 0.5 microns deep is removed with each pulse of said pulsed laser beam.

37. (Not Amended) The method for performing ophthalmic surgery according to claim 24, wherein:

said pulsed laser beam is scanned in circular patterns.

38. (Not Amended) The method for performing ophthalmic surgery according to claim 24, wherein:

said pulsed laser beam is scanned in linear patterns.

~~39.~~ ³³ (Twice Amended) A method for performing ophthalmic surgery comprising:

providing a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, [such that said laser emits a pulsed laser beam having] a repetition rate of at least 1 Hz to 1000 Hz, and an energy level exiting from said output window of said basic laser of 0.5 to 10 mJ per pulse [from said laser]; and

scanning said pulsed laser beam in a substantially overlapping pattern on said corneal tissue such that adjacent ablation spots on a single ablation layer of said corneal tissue significantly overlap one another.

~~40.~~ (Not Amended) The method for performing ophthalmic surgery according to claim 39, wherein:

said pulsed laser beam has a spot size on said corneal tissue of no greater than 1 mm.

~~41.~~ ⁴⁷ (Amended) The method for performing ophthalmic surgery according to claim ~~39~~, wherein: [successive]

pulses of said pulsed laser beam corresponding to adjacent ablation spots on said single ablation layer overlap one another by [are overlapped] at least 50 percent.

~~43.~~ (Not Amended) The method for performing ophthalmic surgery according to claim 39, wherein:

said pulsed laser beam is pulsed at a repetition rate of at least 50 Hz.

44. (Not Amended) The method for performing ophthalmic surgery according to claim 39, wherein:

said pulsed laser beam is scanned synchronously with said pulses of said pulsed laser beam.

45. (Not Amended) The method for performing ophthalmic surgery according to claim 39, wherein:

an area of corneal tissue 0.05 to 0.5 microns deep is removed with each pulse of said pulsed laser beam.

46. (Not Amended) The method for performing ophthalmic surgery according to claim 39, wherein:

said pulsed laser beam is scanned in circular patterns.

47. (Not Amended) The method for performing ophthalmic surgery according to claim 39, wherein:

said pulsed laser beam is scanned in linear patterns.

48. (Amended) A method of performing laser ablation on tissue, said method comprising:

providing a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, [such that said laser emits a pulsed laser beam having] a repetition rate of 1 Hz to 1000Hz, and an energy level exiting from said output window of said basic laser of no greater than 10 mJ per pulse [from an output coupler of said laser];

providing a galvanometer scanner; and

significantly overlapping adjacent ablation spots on a single ablation layer of said tissue by controlling said pulsed output beam with said galvanometer scanner to provide a substantially overlapping pattern of beam pulses on said tissue.

⁵³
49. (Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

D6 [an orientation of] said substantially overlapping pattern is achieved by placing said ablation spots on said single ablation layer of said tissue in random order [using randomized scanning of said pulsed output beam on said tissue].

53. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said ultraviolet wavelength is in a range of 193 to 215 nm.

54. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said ultraviolet wavelength is 193 nm.

55. (Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

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said pulsed output laser beam has an energy level exiting from said output window of said basic laser in a range of 0.05 to 10 mJ per pulse.

57. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said pulsed output beam has a spot size on said tissue of no greater than 1 mm.

58. (Not Amended) The method of performing laser ablation on tissue according to claim 55, wherein:

said pulsed output beam has a spot size on said tissue of no greater than 1 mm.

59. (Not Amended) The method of performing laser ablation on tissue according to claim 50, wherein:

said pulsed output beam has a spot size on said tissue of no greater than 1mm.

60. (Amended) The method of performing laser ablation on tissue according to claim 48, wherein: [successive]

pulses of said pulsed output beam corresponding to adjacent ablation spots on said single ablation layer overlap one another by [are overlapped] at least 50 percent.

63. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said pulsed output beam is scanned synchronously with said pulses of said pulsed output beam.

64. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

an area of corneal tissue in a range of 0.05 to 0.5 microns deep is removed with each pulse of said pulsed output beam.

65. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said pulsed output beam is scanned in circular patterns.

66. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said pulsed output beam is scanned in linear patterns.

67. (Not Amended) The method of performing laser ablation on tissue according to claim 48, wherein:

said pulsed output beam is scanned in concentric circles.

68. (Not Amended) The method of performing laser ablation on tissue according to claim 67, wherein:

said concentric circles have increasing diameters.

69. (Amended) An apparatus for ablating tissue, comprising:
a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, and [adapted to emit a pulsed output beam having] a repetition rate of 1 Hz to 1000 Hz; and

a scanner constructed and arranged to control said pulsed output beam into a substantially overlapping pattern of beam pulses on said tissue such that adjacent ablation spots on a single ablation layer of said corneal tissue significantly overlap one another.

70. (Not Amended) The apparatus for ablating tissue according to claim 69, wherein:

said substantially overlapping pattern of beam pulses has an orientation which is achieved using a randomized scanning of said pulsed output beam on said tissue.

71. (Amended) The apparatus for ablating tissue according to claim 69, wherein:

said pulsed output laser beam has an energy level exiting from said output window of said basic laser of no greater than 10 mJ per pulse.

72. (Amended) The apparatus for ablating tissue according to claim 69, wherein:

DI0 said scanner is constructed and arranged to overlap adjacent beam pulses corresponding to adjacent ablation spots on said single ablation layer by [on said tissue] at least 50 percent.

DI1 ~~sub~~ 75. (Amended) The apparatus for ablating tissue according to claim 69, wherein:

said basic laser is an excimer laser.

~~sub~~ 76. (Amended) An ophthalmic surgery apparatus for performing corneal refractive surgery by reshaping a portion of a corneal surface, said apparatus comprising:

DI2 a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, and [adapted to emit a pulsed laser beam having] an energy level exiting from said output window of said basic laser of less than 10 mJ per pulse [from said laser]; and

a computer-controlled scanning device coupled to said basic laser to cause a significant overlap of adjacent ablation spots on a single ablation layer [such that pulses of said beam are substantially overlapped] to achieve a smooth ablation of corneal tissue in an overlapped area between adjacent ablation spots.

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D13 78. (Amended) A method of performing corneal refractive surgery by reshaping a portion of corneal surface, said method comprising:
pulsing [having] a basic laser having an output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, a repetition rate of 1 to 1000 pulses per second, and an energy level exiting from said output window of said basic laser of no greater than 10 mJ per pulse; and

substantially overlapping adjacent ones of a plurality of ultraviolet laser beam pulses over [an area of] a single ablation layer on a corneal surface sufficient to ablate a depth of between 0.05 and 0.5 microns of corneal tissue per ultraviolet laser beam pulse [; said laser beam pulses having an energy level of no greater than 10 mJ per pulse from an output coupler of said laser; and said laser beam pulses having a pulse repetition rate of 1 to 1000 pulses per second].

80. (Not Amended) The method of performing corneal refractive surgery by reshaping a portion of a corneal surface according to claim 79, further comprising:

selecting a scanner to scan said overlapping plurality of laser beam pulses, said scanner deflecting said laser beam pulses a predetermined angle.

81. (Not Amended) The method of performing corneal refractive surgery by reshaping a portion of a corneal surface according to claim 80, wherein:

said selected scanner is a galvanometer scanner.

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82. (Amended) An ophthalmic surgery apparatus, comprising:
a basic laser having an output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, and [adapted to emit a pulsed beam] an energy level exiting from said output window of said basic laser of less than about 10 mJ per pulse [from said laser]; and

a computer-controlled scanning device coupled to said basic laser to cause a significant overlap of adjacent ablation spots on a single ablation layer of [pulses of said pulsed laser beam on] said corneal surface to achieve a smooth ablation of corneal tissue in an overlapped area between adjacent ablation spots.

83. (Not Amended) The ophthalmic surgery apparatus according to claim 82, wherein:

said pulses are overlapped in a range of 50 to 80 percent.

85. (Not Amended) The ophthalmic surgery apparatus according to claim 82, wherein:

said pulsed beam has a spot size on said corneal tissue of less than or equal to 2 mm.

87. (Not Amended) The ophthalmic surgery apparatus according to claim 82, wherein said scanning device comprises:

a galvanometer.

88. (Not Amended) The ophthalmic surgery apparatus according to claim 87, wherein:

said repetition rate of said laser is synchronized with said galvanometer.

89. (Not Amended) The ophthalmic surgery apparatus according to claim 82, wherein:

successive pulses of said pulsed beam are rotated through a linear-scan angle by said scanning device.

90. (Amended) A method for performing corneal refractive surgery by reshaping a portion of corneal surface, comprising:

selecting a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, [such that said laser emits a pulsed output beam of ultraviolet wavelength and having] and an energy level exiting from said output window of said basic laser of less than 10 mJ/pulse [from said laser];

selecting a scanning mechanism for scanning said pulsed output laser [output] beam;

coupling said pulsed output laser beam to said scanning mechanism for scanning said pulsed output laser beam over [a predetermined] said corneal surface;

controlling said scanning mechanism to deliver [the] said scanning pulsed output laser beam in [an] a substantially overlapping pattern [onto a plurality of positions] on said corneal surface such that adjacent ablation spots on a single ablation layer of said corneal tissue significantly overlap one another to at least one of photoablate and photocoagulate corneal tissue; and

removing from 0.05 to 0.5 microns of corneal tissue per pulse [overlapped to remove tissue to a desired depth], whereby a patient's vision is corrected by said reshaping of said portion of said corneal surface of said patient's eye.

91. (Amended) A method for performing ophthalmic surgery, comprising:

providing a basic laser having a pulsed output laser beam of a fundamental ultraviolet wavelength within a range of 193-220 nm exiting from an output window of said basic laser, [such that said laser emits a pulsed ultraviolet laser beam having] and an output energy level exiting from said output window of said basic laser of no greater than 10 mJ/pulse [from said laser];

applying said pulsing ultraviolet laser beam onto corneal tissue; and scanning said pulsing laser beam in a purposefully substantially overlapping pattern on said corneal tissue such that adjacent ablation spots on a single ablation layer of said corneal tissue significantly overlap one another.

93. (Not Amended) The method of performing ophthalmic surgery according to claim 91, wherein:

said pulsing ultraviolet laser beam is pulsed at a repetition rate of 1 to 1000 Hz.

94. (Not Amended) The method of performing ophthalmic surgery according to claim 91, wherein:

said pulsing ultraviolet laser beam is sufficient to ablate a depth in a range of 0.05 and 0.5 microns of corneal tissue per pulse.

95. (Not Amended) The method of performing ophthalmic surgery according to claim 91, wherein:

said substantially overlapping pattern is achieved using a randomized scanning of said pulsing laser beam on said corneal tissue.

90 97. (Amended) The method of performing ophthalmic surgery according to claim 91⁸⁶, wherein: [successive]

pulses of said ultraviolet laser beam corresponding to adjacent ablation spots on said single ablation layer overlap one another by [are overlapped] at least 50 percent.

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98. (Amended) The method of performing ophthalmic surgery according to claim 91⁸⁶, wherein: [successive]

pulses of said ultraviolet laser beam corresponding to adjacent ablation spots on said single ablation layer overlap one another [are overlapped] in a range of 50 to 80 percent.

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105. (Amended) The method for performing corneal refractive surgery according to claim 90, wherein [:] said scanning mechanism comprises:
a galvanometer.

106. (Not Amended) The method for performing corneal refractive surgery according to claim 90, further comprising:
aligning a center of said scanning laser beam onto said corneal surface with a visible aiming beam.

Remarks

Claims 1-24, 26, 28-30, 32, 35-41, 43-49, 53-55, 57-60, 63-72, 75, 76, 78, 80-83, 85, 87-91, 93-95, 97, 98, 105 and 106 remain pending in the application.

Stipulation that Lai is prior art

The Applicants hereby stipulate that PCT Application No. PCT/US92/09625 filed internationally on November 5, 1992, claiming priority from U.S. Appl. No. 788,424 filed November 6, 1991, ("Shui Lai application")

while bearing a publication date later than the filing of the present application, nevertheless constitutes the state of the art at the time of the present invention. Thus, the Applicants admit *a priori* that any U.S. patent which might issue in the future as a counterpart to PCT/US92/09625 may be considered today by the Examiner as prior art.

This statement is intended to moot any suspension of the present application pending disposition of the Shui Lai application, as suggested by the Examiner, and is intended to instead allow the Examiner to consider the merits of the present application in light of the teachings of Shui Lai.

Shui Lai reference

The numerous distinctions of the claims of the present invention from the teachings of Shui Lai are discussed in detail in the First Supplemental Amendment filed on September 8, 2000. The Examiner is respectfully requested to review that Amendment with respect to his consideration of Shui Lai.

In particular, as discussed in the First Supplemental Amendment, Shui Lai teaches the use of a fundamentally **infrared, high power** laser (150 mJ or greater exiting from an output window of the basic laser) scanned in a **non-overlapping** manner, with offsets of pulse locations being caused by intentional offsets of ablation layers.

This constitutes three separate and important distinctions from the claims of the present invention, which variously recite a fundamentally ultraviolet, low power laser (10 mJ or less from an output window of a basic laser) scanned in a purposefully, substantial overlapping manner (50-80%) on a single ablation layer.

Supported in specification

The following discusses support for such distinctions as recited in the claims using references to the specification of the original patent.

Support for: 10 mJ or less exiting from the output window of a basic laser

The contrasts between the prior art high power lasers (100 mJ and greater) and the low power laser (10 mJ exiting from the output window of the basic laser) used in the disclosed embodiments of the present invention are clearly explained in the specification to one of ordinary skill in the art.

For instance, the present invention discloses the use of a basic laser 10 in Fig. 1 (not the entire laser head **20** including the scanning device and other optics) as including a compact, argon fluoride excimer laser (at 193 nm) with repetition rate of (1-1,000) Hz, and energy per pulse of (0.5-10) mJ. (col. 8, lines 61-64) In another preferred embodiment, the basic laser **10** is a compact, low-cost, low-power (energy of 1 to 10 mJ per pulse) argon fluoride excimer laser at 193 nm. (col. 4, lines 52-54) These energy levels (less than 10 mJ) relates to the energy of the laser beam exiting the basic laser 10, not to an energy level of the laser beam applied to the corneal surface. This would be clear to a person of ordinary skill in the art.

In the Background of the Invention section, it is explained that an object of the invention is to provide an overlapping scanning system which enables use of a low-energy basic laser. (Col. 1, lines 40-44)

In contrast, prior art systems required high powered lasers having energy of (100-300 mJ) per pulse from the laser cavity, or (30-40 mJ) per pulse delivered onto a corneal surface. (col. 2, lines 17-19) These prior art systems are explained to be less than 10% efficient in converting energy from the output of the laser window to the corneal surface. (col. 1, lines 40-41; col. 3, lines 1-3) Not only are such high power basic lasers inefficient, they exhibit higher system and maintenance costs (e.g., more gas), larger size/weight, and greater sensitivity to environmental conditions such as temperature and moisture. (col. 2, lines 27-32)

An essential feature of the present invention is explained as the use of a laser which requires less energy, e.g., ranging between 0.05-10 mJ per pulse, to enable one to make refractive lasers at lower cost, smaller size, and

with less weight (by a factor of 5-1) than that of high power prior art lasers. (col. 4, lines 6-13)

Support for: Overlapping such that adjacent spots on a single ablation layer significantly overlap one another

The present inventors recognized that non-overlapping pattern ablation systems (e.g., L'Esperance and Lai) introduce additional complexity. For instance, non-overlapping pattern ablation systems require substantially uniform density laser beams, which in turn requires high power basic lasers (100-200 mJ) (col. 2, lines 40-45) Non-overlapping systems also require registration accuracy to within a desired roughness of the final surface.

Typically, because of the non-overlapping patterns, such equipment requires complex apparatus to select a uniform density section of the laser beam. (col. 2, line 65-col. 3, line 1) This further reduces efficiency between the energy output from a window of the conventional high power basic laser and ablation energy applied to the cornea, resulting in the tendency of prior art systems to include higher power basic lasers-not lower power basic lasers.

The present invention went against this conventional wisdom by using a much, much smaller basic laser, having much, much less power than those in conventional systems. Because the basic laser had much lower power, efficiency was important as between the energy output from an output window of the basic laser and the energy ultimately applied to the corneal tissue.

Significant overlap of pulses provided a solution. Significant overlap of pulses not only reduced or eliminated the need for a masking or selection of only a uniform density portion of the laser beam, but because of the higher efficiency (e.g., 50% efficiency as compared to 10% efficiency in prior art systems), low power lasers could be implemented.

Significantly overlapped pulses is not obvious

Overlapping ablation pulses is straight forward from conventional equipment which purposely avoided overlap but for overlap caused by tolerances in the equipment. Smooth ablation layers is important in achieving an overall

smooth ablation. L'Esperance and Lai each teach that smooth ablation can be best achieved by using a mosaic of pulses, preferably not overlapping. While Lai recognized that some overlap might occur due to tolerances, those of skill in the art would appreciate that where such overlap did occur, it caused deviations from a smooth ablation in that ablation layer, which was to be avoided.

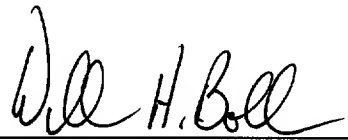
Moreover, according to prior art systems, the greater the overlap, the longer the procedure (which was to be avoided). Thus, those of ordinary skill in the art would have, at best, tended to *reduce* overlapping, if any, not only to achieve the desired smooth ablation, but also to reduce procedure time.

The present invention balances a recognition of a generally longer procedure time necessary to overlap pulses, against numerous advantages with a low power laser, e.g., reduced size/weight of the basic laser, avoidance of ridges present in prior art systems, etc., resulting in a reduction in cost of equipment.

Conclusion

It is respectfully submitted that the subject application is in condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully submitted,



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GP 3739

TRANSMITTAL LETTER (Small Entity)

Application Number: 09/084,441

Group Art Unit: 3739

Filed: May 27, 1998

Examiner Name: Michael Peffley

Applicant: LIN

Attorney Docket Number: 62-575

TITLE: OPHTHALMIC SURGERY METHOD USING NON-CONTACT SCANNING LASER

**ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231**

SIR:

Transmitted herewith is a Second Supplemental Amendment in the above-identified application.

Small entity status of this application has been established under 37 C.F.R. 1.27 by a verified statement previously submitted.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED					
	CLAIMS REMAINING AFTER Amendment	HIGHEST # PREV. PAID FOR	#OF EXTRA CLAIMS	RATE	ADDITIONAL FEE
Total Claims	80 -	106	0	x \$9 =	\$0
Independent Claims	10 -	10	0	x \$39 =	\$0
Multiple Dependent Claim(s), if applicable					\$0
TOTAL ADDITIONAL FEE:					\$0

No fee is believed to be due. However, should a fee be assessed, the commissioner is **hereby authorized to charge** any fees required under 37 C.F.R. 1.16 or any patent application processing fees under 37 C.F.R. 1.17 associated with this communication, or to credit any overpayment to **Deposit Account No. 50-0687 under order No. 62-575**.

Respectfully submitted,

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Date: October 25, 2000

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